IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:	Mohamed Alam
SERIAL NO.:	10/046,061
FILED:	January 11, 2002
EXAMINER:	Corbin, Arthur L.
GROUP ART UNIT:	1761
MAILING DATE OF ACTION:	October 15,2004
TITLE:	COMPOSITION AND PROCESS FOR CLEANING AND DISINFECTING FOOD PRODUCTS

SECTION 132 DECLARATION

I, John Bonnes, hereby declare:

I am a chemist with more than 15 years experience in chemical laboratory analysis of food for Ameritech Laboratories of 128-17 20th Avenue, College Point, NY 11356.

I have performed laboratory work for Mohamed Alam for over ten years, analyzing and testing his "Clean-a-Meal" product.

I tested the Clean a Meal product which is the subject of his patent application on various meats and foods, upon which the present regular examinable patent is based.

1. I am attaching copies of two separate studies which were run that address the shelf life issue. The first study is Ameritech #123216 dated 06 Nov. 01. This study treated both hotdogs and sausages with bacterial cultures. The treated hot dogs and sausages were then divided into two groups. One of the groups was treated with Clean-A-Meal, while the other group received no further treatment. Samples from both groups were tested over a period of two weeks for bacterial counts. The non-Clean-A-Meal treated samples had bacteria counts which increased to very high levels while the Clean-A-Meal treated samples had counts which remained low. Since the bacterial types used in this study represent a broad range, the effectiveness of Clean-A-Meal in this study

indicates that it will provide significant improvement in shelf life for these types of products.

The second study, Ameritech #22512 dated 10 Sep. 02, involved the addition of Clean-A-Meal to hamburger meat. In this study, Clean-A-Meal significantly retarded bacterial growth. Since bacterial growth is almost always responsible for hamburger meat becoming inedible, Clean-A-Meal addition will provide extended shelf life.

2. To date no direct comparison of Clean-A-Meal to vinegar has been performed which compares the relative effectiveness of both for either bacterial kill or bacterial inhibition. However, both hamburger meat and hotdogs have been treated with vinegar solutions which had equivalent acid levels and half equivalent acid levels in comparison to samples treated with Clean-A-Meal. The purpose of the comparison was to determine if such vinegar treatment should be compared to Clean-A-Meal. The initial comparison was based on tasted, i.e. would the vinegar treatment result in meat which was acceptable from a taste point of view. The vinegar treated samples were judged to be unacceptable in taste and as such vinegar alone treatment would not be a practical treatment for general microbiological control. Since it was unlikely that any treatment that had less than half the acidity of Clean-A-Meal and no other components could provide microbiological control at anywhere near the effectiveness of CAM, no direct microbiological effectiveness comparison was run.

3. The following are the comments regarding the "prior art" cited by the patent office.

A. "Recipes: the cooking of India" This item shows several recipes which incorporate some (but not all) of the ingredients in CAM. There is no evidence that the ingredients when incorporated individually have any significant microbiological control properties and further there is no evidence that is the purpose for their inclusion.

B. Patent #18,345, AD 1911 "Method of Preserving Fish and the Like". This patent has only Acetic Acid (principal component of vinegar) and salt as

common ingredients with CAM. It also contains ethyl alcohol which is absent in CAM. The combination of acetic acid and ethanol will result in the production of ethyl acetate to varying degrees depending on the storage conditions. Any ethyl acetate produced will almost surely participate in any microbiological control activity. However, as ethyl acetate is built up, eventually the organoleptic properties of the treated food will make it unpalatable. Also as ethyl acetate is increased, the acetic acid and ethyl alcohol are both decreased.

C. Patent #3,875,313 "Method of treating meat" This patent involves the mixing of anhydrous sodium tripolyphosphate and lemon juice which results in a dry granular mixture. The mode of action of this patent is a combination of antioxidant activity (due primarily to the ascorbic acid in the lemon juice) and chelation (due to the tripolyphosphate). The amount of lemon juice which can be added to the mixture is limited due to the fact that a dry granular powder is desired. When the lemon juice is mixed with the NaTPP, it binds to and coats the surface of the NaTPP particles. The amount of lemon juice which can bind to the NaTPP particles is a function of the amount of surface area of the NaTPP particles. As the average particle size of a given mass of a NaTPP decreases, the total surface area increased and the amount of lemon juice which is required to coat the particles while still achieving a dry end product increases. Any lemon juice above his limiting amount will result in a wet mix. Also, the addition of an excess of lemon juice would result in the hydrolysis of the tripolyphosphate to monophosphate and destroy the chelation effect of the TPP. The amount of lemon juice used to maintain a dry mix is far less than the amount in CAM.

Further, the addition of the lemon juice (an acidic material) with NaTPP (an alkaline material) would result in a neutralization of the acidity of the lemon juice and thereby negate the use of the lemon juice's acidity in any microbiological control activities.

D. Patent #3,843,805 "Base composition for

preparing food products". The three ingredients listed in this patent are: pregelatinized starch, calcium acetate and sodium caseinate. None of these ingredients are common to the CAM ingredients. Two of them, the Ca and Na ingredients, are alkaline in nature and in no way would produce any effect similar to CAM or the individual ingredients in CAM.

E. Article "J. Bact. Vol 40, 1940". This paper describes the use of vinegar in the presence of salt and sucrose (common table sugar) to inhibit microorganisms. While the use of vinegar with and without salt has been used for many years for its preservative effect, its limitations have prevented it from being a universal microbiological control agent. The vinegar works primarily by lowering the pH to a point where some bacteria will either stop growing or die. The salt works by increasing the osmotic pressure of the environment that encompasses the bacteria and thereby altering the internal composition of the bacteria which prevents them from growing. CAM is a much more complex mixture with a number of ingredients which act synergistically to produce the full effectiveness of the composition. CAM, in addition to providing a very low pH environment for the bacteria, contains relative high levels ascorbic acid from both the lemon and lime juices. The ascorbic acid reacts with oxygen, thereby denying its use by the bacteria which need it to grow. The lemon and lime juices also contain a compound called limonene. This is a component of the essential oils which give lemon and lime juice their characteristic flavor. Limonene has been shown to be bactericidal in its own right. Curcumin has been shown to have microbiological control properties of its own. What makes CAM unique, is not the individual ingredients with their individual properties, but the synergism which results from their combination to produce a mixture with a much broader spectrum of microbiological control properties while not yet producing treated items with unacceptable organoleptic properties.

F. "Dictionary of Herbs, Spices, Seasonings and Natural Flavorings" Vindaloo Mixture. This item shows a recipe which incorporate some (but not all) of the

ingredients in CAM. While these ingredients when incorporated individually may have some microbiological control properties, it is highly unlikely that they would achieve anywhere near the effectiveness that is achieved by their inclusion in CAM. Further, there is no evidence that the purpose for their inclusion is microbiological control.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

John Bonnes

Dated: April 12, 2005

PAT132

AMERITECH LABORATORIES

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08-Nov-01

To: Mr. Mohamed B. Alan
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123216

Subject: Clean-A-Meal Hot Dog study.

The purpose of this study is to determine the effectiveness of "Clean-a-Meal" as a agent to control the growth of microorgnisms on packaged hotdogs.

Locally purchased hotdogs were used for this study. All test items were examined for freshness. Immediately prior to application of the bacterial culture, each hotdog was immersed in boiling water for 10 seconds followed by cooling for a minimum of 2 minutes before the application of the bacteria culture.

Stock cultures of the following bacteria were prepared: E. Coli, Salmonella typhimurium, Listeria Monocytogenes, Staphylococcus Aureus and Clostridium Perfringins. These cultures were prepared so as to have approximately 10 million bacteria per milliliter. For application the cultures were diluted by a factor of 5, 50 and 500.

The 2 millliters of each culture was applied to to the surface of the hotdog, covering as much of the surface as possible. The culture was spread evenly and allowed to dry for 4 hours. At the end of four hours, the hotdogs were coated with "Clean-A-Meal" spraying so as to be completely covered. The sprayed hotdogs were placed in sterile plastic bags, three to a bag. Control groups of each culture were also prepared. The bags with the Clostridium cultures were vacuum sealed, all others were closed with only a small amount of air remaining. After closing, the bags were placed in a refrigerator at 40 degrees F. until removed for analysis.

Prior to analysis, the bags were removed from the refrigerator and allowed to come to room temperature. The hot dogs were then rinsed under a stream of cool water to remove the Clean-A-Meal coating. No scrubbing was applied. The hot dogs were then placed in 100 ml of sterile buffer prior to plating the buffer. The rinsing procedure was applied to the samples run on day 0 which were not refigerated.

Results:

Day 0

High Level Control	E. Coli	Salmon.	Listeria	Staph.	Clostrid.
1	2,760,000	1,300,000	2,760,000	867,000	907,000
2	1,950,000	1,420,000	1,140,000	765,000	973,000
3	2,320,000	1,160,000	2,250,000	843,000	892,000
avg	2,343,333	1,293,333	2,050,000	825,000	924,000

Clean-A-Meal					
1	37600	8560	59200	13100	32000
2	41600	7150	53200	11700	25200
3	34100	7320	51400	11900	31000
avg	37767	7677	54600	12233	29400
avg % reduction	98.39	99.41	97.34	98.52	96.82

Day 0

Low Level Control	E. Coli	Salmon.	Listeria	Staph.	Clostrid.
1	24,100	12,700	36,200	10,700	12,100
2	20,300	15,200	28,400	11,400	10,600
3	18,300	14,700	31,000	10,100	10,200
avg	20,900	14,200	31,867	10,733	10,967

Clean-A-Meal					
1	126	530	592	131	320
2	328	450	532	117	252
3	276	662	514	119	310
avg	243	547	546	122	294
avg % reduction	98.84	96.15	98.29	98.86	97.32

Results:

Day 1

High Level Control	E. Coli	Salmon.	Listeria	Staph.	Clostrid.
1	2,150,000	1,370,000	2,840,000	875,000	657,000
2	2,310,000	1,290,000	2,720,000	732,000	542,000
3	1,820,000	1,520,000	2,430,000	804,000	743,000
avg	2,093,333	1,393,333	2,663,333	803,667	647,333
Clean-A-Meal					
1	29500	5780	50400	15200	22500
2	34200	6320	62500	18300	26900
3	25100	7070	50300	12600	19400
avg	29600	6390	54400	15367	22933
avg % reduction	98.59	99.54	97.96	98.09	96.46

Day 1

Low Level Control	E. Coli	Salmon.	Listeria	Staph.	Clostrid.
1	18,300	13,500	33,700	11,800	9,600
2	19,700	14,700	32,900	12,600	7,200
3	16,200	15,900	27,600	9,500	10,400
avg	18,067	14,700	31,400	11,300	9,067
Clean-A-Meal					
1	333	576	322	108	156
2	249	423	572	85	182
3	385	486	287	128	295
avg	322	495	394	107	211
avg % reduction	98.22	96.63	98.75	99.05	97.67

Results:

Day 2

High Level Control	E. Coli	Salmon.	Listeria	Staph.	Clostrid.
1	2,830,000	1,720,000	2,790,000	1,020,000	594,000
2	3,140,000	1,420,000	3,040,000	970,000	627,000
3	2,350,000	1,960,000	2,560,000	1,110,000	757,000
avg	2,773,333	1,700,000	2,796,667	1,033,333	659,333
Clean-A-Meal					
1	25600	15600	43200	23100	11800
2	22000	17400	50200	19300	15600
3	27200	18200	51500	20700	18200
avg	24933	17067	48300	21033	15200
avg % reduction	99.10	99.00	98.27	97.96	97.69

Day 2

Low Level Control	E. Coli	Salmon.	Listeria	Staph.	Clostrid.
1	16,100	15,600	28,200	14,700	7,200
2	18,800	18,300	31,600	13,300	9,400
3	15,600	14,700	27,200	16,200	8,800
avg	16,833	16,200	29,000	14,733	8,467
Clean-A-Meal					
1	293	486	336	87	122
2	268	527	295	152	176
3	367	445	313	98	198
avg	309	486	315	112	165
avg % reduction	98.16	97.00	98.91	99.24	98.05

Results:

Day 4

High Level Control	E. Coli	Salmon.	Listeria	Staph.	Clostrid.
1	3,950,000	1,820,000	2,790,000	1,010,000	702,000
2	3,320,000	2,230,000	3,130,000	1,050,000	657,000
3	2,760,000	2,470,000	2,980,000	1,080,000	602,000
avg	3,343,333	2,173,333	2,966,667	1,046,667	653,667

Clean-A-Meal					
1	20800	18800	44700	28000	14100
2	22900	15600	38900	17200	10400
3	23500	12700	40300	13100	6500
avg	22400	15700	41300	19433	10333
avg % reduction	99.33	99.28	98.61	98.14	98.42

Day 4

Low Level Control	E. Coli	Salmon.	Listeria	Staph.	Clostrid.
1	21,300	18,900	26,000	19,400	10,400
2	20,700	13,800	29,600	20,300	8,300
3	18,200	17,200	36,100	22,600	7,800
avg	20,067	16,633	30,567	20,767	8,833

Clean-A-Meal					
1	156	336	170	101	113
2	453	367	226	75	124
3	245	408	256	83	206
avg	285	370	217	86	148
avg % reduction	98.58	97.77	99.29	99.58	98.33

Results:

Day 7

High Level Control	E. Coli	Salmon.	Listeria	Staph.	Clostrid.
1	5,640,000	2,070,000	2,990,000	1,420,000	814,000
2	4,360,000	3,210,000	4,720,000	1,250,000	727,000
3	5,250,000	2,670,000	4,230,000	1,320,000	733,000
avg	5,083,333	2,650,000	3,980,000	1,330,000	758,000
Clean-A-Meal					
1	34600	12700	33500	13700	10600
2	18200	14300	42600	22400	9600
3	24300	14800	32100	20600	12500
avg	25700	13933	36067	18900	10900
avg % reduction	99.49	99.47	99.09	98.58	98.56

Day 7

Low Level Control	E. Coli	Salmon.	Listeria	Staph.	Clostrid.
1	34,800	22,100	45,600	28,300	7,100
2	38,200	17,800	38,000	16,500	11,400
3	23,200	21,700	42,000	25,700	9,200
avg	32,067	20,533	41,867	23,500	9,233
Clean-A-Meal					
1	220	550	143	156	92
2	180	360	192	62	180
3	300	290	243	112	240
avg	233	400	193	110	171
avg % reduction	99.27	98.05	99.54	99.53	98.15

Results:

Day 14

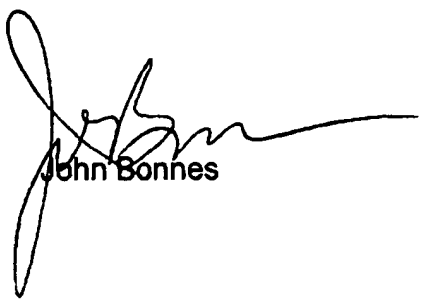
High Level Control	E. Coli	Salmon.	Listeria	Staph.	Clostrid.
1	6,240,000	2,850,000	4,770,000	1,620,000	779,000
2	7,500,000	2,680,000	4,480,000	1,170,000	882,000
3	6,300,000	3,210,000	3,950,000	1,720,000	823,000
avg	6,680,000	2,913,333	4,400,000	1,503,333	828,000

Clean-A-Meal					
1	22600	9600	51000	14000	11200
2	28500	8200	28000	12300	8400
3	14600	16700	22100	16300	9500
avg	21900	11500	33700	14200	9700
avg % reduction	99.67	99.61	99.23	99.06	98.83

Day 14

Low Level Control	E. Coli	Salmon.	Listeria	Staph.	Clostrid.
1	55,000	28,000	44,100	33,100	8,400
2	44,000	23,200	46,200	15,000	12,100
3	52,000	29,000	39,000	28,900	7,800
avg	50,333	26,733	43,100	25,667	9,433

Clean-A-Meal					
1	160	330	180	130	110
2	183	180	106	87	75
3	254	300	200	65	175
avg	199	270	162	94	120
avg % reduction	99.60	98.99	99.62	99.63	98.73



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10-Sep-02

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225213

Subject: Hamburger shelf life study.

The purpose of this study is to determine the effect, if any, of the addition of "Clean-A-Meal" (CAM) to hamburger meat on its refrigerated shelf life.

Clean-A-Meal was added to hamburger meat at a rate of one tablespoon (15 milliliter per pound of meat. The meat massaged and blended thoroughly so as to achieve a complete and uniform distribution of the CAM in the sample. The meat was allowed t sit at refrigerator temperature of 40 deg. C. for 3 days. An equal sample of hamburge meat from the same lot was set aside in the refrigerator for the same 3 days to serve a control.

This is a portion of the same meat which was used for the taste test study. The first sample which was taken from both the test and the control sample was done on the c of the taste test. Subsequent samples were taken at 2 day intervals .

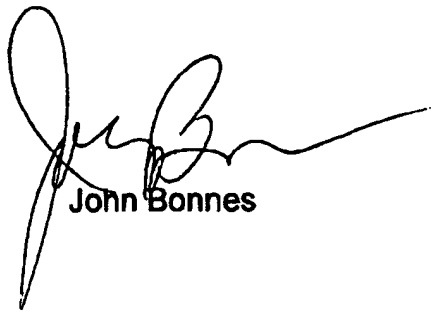
Initial sampling	Control	Test
Total Bacteria Count/gm	12,600	4700
Total Coliform Count/gm	3620	1050
E. Coli/10	Negative	Negative
Salmonella/10	Negative	Negative
Listeria/10	Negative	Negative

Total Bacteria Count/gm

Day #	Control	Test
0	12,600	4700
2	28900	6540
4	73400	9640
6	192000	18300
8	394000	27400
10	725000	44200

Total Coliform Count/gm

Day #	Control	Test
0	3620	1050
2	9400	1320
4	26300	1960
6	49100	4490
8	115000	6800
10	231000	88700



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